



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0032]

Agency Information Collection Activities; Proposed Collection; Comment Request;
Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User
Fee Amendments of 2008

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on paperwork requirements for an electronic form (e-form), to collect distribution reports for antimicrobials in food producing animals.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Denver Presley, II,
Office of Information Management,
Food and Drug Administration,
1350 Piccard Dr.,
PI50-400B,
Rockville, MD 20850,
301-796-3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

(2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008--Federal Food, Drug, and Cosmetic Act, Section 512(l)(3) (OMB Control Number 0910-0659)--Revision

Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA II) (Public Law 316) amended section 512 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b) by, among other things, creating section 512(l)(3) to require that the sponsor of each new animal drug that contains an antimicrobial agent submit an annual report to FDA on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. The legislation was enacted to address the problem of antimicrobial resistance and to help ensure that FDA has the necessary information to examine safety concerns related to the use of antibiotics in food-producing animals (154 Congressional Record H7534).

Each report must specify: (1) The amount of each antimicrobial active ingredient by container size, strength, and dosage form; (2) quantities distributed domestically and quantities exported; and (3) a listing of the target animals, indications, and production classes that are specified on the approved label of the product. The first report under the statute was to be submitted not later than March 31, 2010. The report covered the period of the preceding calendar year and included separate information for each month of the calendar year.

We are now seeking to further implement the statutory requirements of ADUFA II and enhance its public health and safety mission as envisioned by Congress by introducing an electronic form for the submission of the required annual reports under ADUFA II. The e-form FDA 3744a will enable sponsors to submit electronically and capture all information as mandated by Section 105 of ADUFA II. Form FDA 3744 will continue to be designated for paper submissions.

List of information required on form FDA 3744 and e-form FDA 3744a:

- Application Type
- Application Number
- Firm Name
- Dosage Form(s)
- Production Class(es)
- Animal Species--Food Animal or Food and Non-Food Animal
- Indications
- Active Ingredient(s)
- Domestic Quantities
 - Unit of Measure for All Active Ingredients
 - Calendar Year
 - Quantity Sold by Month for All Active Ingredients
 - Annual Total Sold for All Active Ingredients
- Export Quantities
 - Unit of Measure for All Active Ingredients
 - Calendar Year

- Quantity Sold by Month for All Active Ingredients
- Annual Total Sold for All Active Ingredients
- Individual Product Information for All Active Ingredients
 - Dosage Form
 - Container Size
 - Container Units
 - Active Ingredient Strength
- Quantities of Individual Products Sold or Distributed (Domestic and Export)
 - Unit of Measure for All Active Ingredients
 - Quantity Sold by Month for All Active Ingredients
 - Annual Total Sold for All Active Ingredients

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

FD&C Act Section 512(l)(3)	Form FDA No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Capital Costs
Annual Reports for Sponsors With Active Applications-- Paper Submission	3744	14	5.9	83	60	4,980	\$6,975
Annual Reports for Sponsors With Active Applications-- Electronic Submission	e-Form 3744a	12	6.7	80	50	4,000	
Annual Reports for Sponsors With Inactive Applications-- Paper Submission	3744	13	6.2	81	2	162	

Annual Reports for Sponsors With Inactive Applications-- Electronic Submission	e-Form 3744a	11	7.3	80	2	160	
Total						9,302	

¹There are no operating and maintenance costs associated with this collection of information.

The total annual responses were calculated by multiplying the number of respondents times the number of responses per respondent. Total burden hours were calculated by multiplying total annual responses times the average burden per response.

As explained in the supporting statement for the subject collection of information (OMB control number 0910-0659), the initial one-time capital costs are for the design of the report. Here, e-form FDA 3744a and reporting via the Electronic Submission Gateway are provided by FDA. Thus, the remaining cost, as described in approved OMB control number 0910-0659 is \$6,975 per year (3 hours x \$46.50 wage rate x 50 sponsors) = \$6,975. FDA believes that the sponsors already possess the computer equipment needed to prepare the report so that additional capital expenditures will not be necessary.

Table 2.--Estimated Annual Recordkeeping Burden¹

Revised 21 CFR 514.80(b)(5)	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
All Applicants	34	1	34	2	68

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Total annual records were calculated by multiplying the number of recordkeepers times the number of records per recordkeeper. Total hours were calculated by multiplying total annual records times the average burden per recordkeeping.

Dated: January 10, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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